UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

PASTEL CARTEL LLC
13326 Immanuel Road
Pflugerville, Texas 78660,

Plaintiff,

v.

U.S. FOOD AND DRUG ADMINISTRATION;
ROBERT M. CALIFF, M.D., Commissioner of Food and Drugs, in his official capacity,
10903 New Hampshire Avenue
Silver Spring, Maryland 20903;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;
XAVIER BECERRA, Secretary of Health and Human Services, in his official capacity,
200 Independence Avenue, S.W.
Washington D.C. 20201,

Defendants.

Case No. 1:23-cv-1010

Jury Demanded

COMPLAINT

Plaintiff Pastel Cartel LLC ("Pastel Cartel" or the "company") hereby files this Complaint against the United States Food and Drug Administration, Robert M. Califf, M.D., Commissioner of Food and Drugs in his official capacity, the United States Department of Health and Human Services, and Xavier Becerra, Secretary of the Department of Health and Human Services in his official capacity (collectively, "FDA" or the "Agency"), and in support alleges as follows:

NATURE OF THE ACTION

1. Through this action, Plaintiff seeks a declaratory judgment that FDA violated the Administrative Procedure Act ("APA") by issuing Refuse to Accept ("RTA") orders for nine

bundled and individual Premarket Tobacco Product Applications ("PMTAs") that Pastel Cartel submitted to FDA covering a total of over 100 electronic nicotine delivery system ("ENDS") products (commonly known as e-cigarettes) that the company manufactures and sells.

2. Plaintiffs contend that FDA acted arbitrarily and capriciously, abused its discretion, proceeded unlawfully and not in accordance with the law, and otherwise failed to cite any substantial evidence in support, when it issued the RTAs because: (i) FDA incorrectly claimed the PMTAs were missing required information and forms when, in fact, such information and forms were included in the applications; (ii) in the few instances where information and forms were not presented in the precise format requested by FDA, the required information was otherwise included in the PMTAs and easily accessible by the Agency; (iii) FDA failed to follow its own internal procedures for conducting PMTA acceptance reviews; and (iv) FDA failed to consider timely-filed PMTA amendments submitted by Pastel Cartel because the Agency incorrectly determined that the amendments were missing required company certifications.

3. Plaintiff seeks: (i) a preliminary injunction staying the RTA orders pending the outcome of this action; (ii) a declaratory judgment finding the RTAs violate the APA and the Due Process Clause of the Fifth Amendment; and (iii) a final judgment setting aside the RTA orders and remanding the PMTAs for further review.

THE PARTIES

4. Plaintiff Pastel Cartel is a corporation headquartered in Pflugerville, Texas. Pastel Cartel manufactures and distributes ENDS products nationwide, including in this district.

5. Defendant United States Food and Drug Administration ("FDA") is a division of Defendant Department of Health and Human Services ("HHS"). The headquarters and principal place of business of FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland, 20903. The

headquarters and principal place of business of HHS is 200 Independence Avenue, S.W., Washington, D.C., 20201. Defendant Robert M. Califf, M.D., is the FDA Commissioner and Defendant Xavier Becerra is the HHS Secretary. Both are sued in their official capacity.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361. This Court has authority to grant declaratory relief requested by the Plaintiff pursuant to 28 U.S.C. §§ 2201 and 2202. This Court has authority to hold unlawful and set aside FDA's actions pursuant to 5 U.S.C. §§ 702 and 706, and to grant injunctive relief under 5 U.S.C. § 705.

7. This Court has personal jurisdiction over Defendants FDA and HHS, as well as Commissioner Califf and Secretary Becerra in their official capacities, as each is an agency or official of the United States government.

8. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) as the district where Plaintiff Pastel Cartel is headquartered.

FACTS

Background on ENDS and Esco Bar Brand ENDS Products

9. There are two broad categories of ENDS – open-systems and closed systems. Open-system devices are run on large, re-chargeable lithium-ion batteries and utilize a tank that consumers re-fill with a flavored e-liquid of their choice. Consumers must purchase bottled e-liquids separately for use in these products. Closed-system devices come in two forms. There are pod- or cartridge-based ENDS that require the user to insert a cartridge pre-filled with e-liquid into the device containing a battery and heating component. These pod-based devices are re-chargeable and employ relatively smaller batteries compared to open-system ENDS devices. The second type of closed-system ENDS devices are known as "disposables." These come with an e-liquid pre-

filled in a sealed reservoir and are then discarded by the consumer after use. There is no removable pod or cartridge component. The batteries in disposable ENDS cannot be re-charged.

10. Pastel Cartel markets a wide variety of ENDS products (over 100 SKUs) that come in a number of device types, nicotine concentrations, and flavors, including the Esco Bar-branded disposable ENDS products and domestically produced bottled e-liquids used in open-system ENDS devices. The disposable ENDS devices are produced by contract manufacturers located in Shenzhen, China and then imported into the U.S., while the company's stand-alone e-liquids are produced and bottled by a third-party contractor in Texas.

ENDS Are Harm Reduction Products

11. Compared to traditional combustible cigarettes, ENDS expose users to far fewer harmful chemicals and generally at much lower levels. Almost all the harm caused by smoking arises from inhaling toxic products of combustion (tar and toxic gases that constitute the smoke from burning tobacco leaf). ENDS instead use electricity to heat a liquid into an aerosol of liquid droplets and do not involve combustion.

12. For example, in 2018, the National Academies of Science, Engineering, and Medicine ("NASEM") completed a comprehensive review of relevant literature, concluding that "*While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes*." NASEM, *Public Health Consequences of E-Cigarettes*, National Academies Press (2018), Summary at 1, https://bit.ly/3qzJLhf.

13. The current Director of FDA's Center for Tobacco Products, Dr. Brian King, recently co-authored a commentary in the scientific journal *Addiction* highlighting the importance of addressing misperceptions among adult smokers about the relative risks of tobacco products which exist on a continuum of risk, with smoked products, such as cigarettes, having the greatest

risk, compared to non-combustible, lower-risk products such as e-cigarettes. Dr. Brian King, et al., *Commentary on Wackowski et al.: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products among Adult Smokers*, Addiction, 1, 1-3 (2023), https://doi.org/10.1111/add.16296.

14. ENDS are also effective in helping adult smokers move away from their smoking habits. In fact, research shows that ENDS outperform the current FDA-approved cessation method, nicotine replacement therapy ("NRT") (e.g., nicotine gums and patches).

15. For instance, the latest Cochrane systematic review – widely considered the gold standard of systematic reviews – concluded, *"There is high-certainty evidence that [e-cigarettes] with nicotine increase quit rates compared to NRT..."* J. Hartmann-Boyce, et al., *Electronic cigarettes for smoking cessation (Review)*, 11 Cochrane Database of Systematic Reviews 2, Abstract at 2, https://tinyurl.com/22jbyw52.

16. A common misperception about ENDS products is that, like cigarettes, they are inherently tobacco-flavored. But the base ingredients used in ENDS do not impart a tobacco or any characterizing flavor. Rather, all flavors in ENDS, including tobacco-flavor, must be added to the e-liquid. Using non-tobacco ENDS flavors (e.g., fruit, mint, menthol) may help adult smokers switch away from cigarettes.

17. For example, one recent study analyzed a nationally-representative survey of adult smokers and concluded, *"Those using flavored e-cigarettes, particularly menthol or mint, are more likely to quit successfully."* Yoonseo Mok, et al., *Associations between E-Cigarette Use and E-Cigarette Flavors with Cigarette Smoking Quit Attempts and Quit Success: Evidence from a U.S. Large, Nationally Representative 2018-2019 Survey*, 25(3) Nicotine Tobacco Research, 541-552, at 541 (2023), https://tinyurl/2j79rdjr.

18. A new study published in *The Lancet* journal further supports the role that ENDS play on cigarette reduction or quitting in the real-world setting. As summarized in the most recent Cochrane review, clinical trials on ENDS are largely focused on smoking cessation. This study aimed to determine the naturalistic uptake, use, and impact of e-cigarettes among adults who may or may not want to stop smoking. The results of the study complement cessation-focused trials, and suggest that unguided ENDS use also leads to smoking cessation, "allaying the notion that causal effects of ENDS on cessation are not reflective of real-world scenario of self-determined use." Matthew J. Carpenter, et al., *Effect of unguided e-cigarette provision on uptake, use, and smoking cessation among adults who smoke in the USA: a naturalistic, randomised, controlled clinical trial,* 102143 The Lancet eClinicalMedicine 1, 1-12 (published online Aug. 15, 2023), https://doi.org/10.1016/j.eclinm.2023.102142.

The Federal Tobacco Control Act and FDA's Deeming Rule

19. In 2009, Congress amended the Federal Food, Drug and Cosmetic Act ("FDCA") by enacting the Family Smoking Prevention and Tobacco Control Act ("TCA"), which gives FDA regulatory authority over the marketing and sale of "tobacco products." 21 U.S.C. §§ 387, *et seq*. Initially, the TCA only governed four types of tobacco products (cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco), but authorized FDA to later "deem" additional tobacco products (such as ENDS) as subject to the TCA. 21 U.S.C. § 387a(b).

20. On August 8, 2016, FDA's "Deeming Rule" went into effect, which applied the TCA to ENDS and other tobacco products. 81 Fed. Reg. 28974 (May 10, 2016). As a result, all ENDS products then on the market, as well as any ENDS commercialized in the future, became immediately subject to the extensive regulatory requirements set forth in the TCA.

21. Among other obligations, Section 910 of the TCA, 21 U.S.C. § 387j, requires that any tobacco product that was not commercially marketed as of February 15, 2007, receive a marketing granted ("MGO") order from FDA prior to being commercially marketed in the United States. Because there were no ENDS products on the market in early 2007 (at least ENDS products as they are known today), all ENDS manufacturers must submit a PMTA to obtain pre-market authorization from FDA before continuing to market and sell their products.

22. By the time the Deeming Rule took effect in 2016, however, there were already tens of thousands of ENDS in the marketplace. To prevent a sudden, mass exit of these products used by millions of adult smokers, FDA established a deferred compliance policy whereby unauthorized ENDS products already on the market on the effective date of the rule (*i.e.*, August 8, 2016) could remain on the market through a future PMTA deadline. Furthermore, products subject to timely-submitted PMTAs could remain on the market without the threat of enforcement for an additional year pending FDA's review of the application. 81 Fed. Reg. at 28977-78.

23. Initially, FDA set the PMTA submission deadline as August 8, 2018. According to FDA, this balanced concerns regarding underage use and continuing to provide access to products adult smokers might be using to move away from more dangerous cigarettes. *Id.*

24. Over the ensuing years, FDA extended the PMTA deadline, finally landing on August 8, 2021. This was designed to provide FDA sufficient time to issue guidance and rules regarding the PMTA process and give manufacturers adequate time to prepare the extensive scientific data necessary to comply with the PMTA requirements. But in response to a lawsuit filed by anti-vaping groups, a federal judge in Maryland eventually moved the due date back to September 9, 2020 and allowed products subject to timely-filed applications to remain on the

market for an additional year (or until September 2021) without the threat of enforcement. *Am. Academy of Pediatrics, et al. v. FDA*, 8:18-cv-00883-PWG (D. Md.) (Dkt. Nos. 127 & 182).

25. FDA has continued to exercise enforcement discretion as to ENDS products with a PMTA currently pending before the Agency. *See* FDA News Release: *FDA Denies Authorization to Market JUUL Products* (updated July 5, 2022), https://tinyurl.com/4nd7m5p6 ("As FDA has stated in the past, unauthorized electronic nicotine delivery system (ENDS) products for which no application is pending, including for example, those with [a marketing denial order], are among our highest enforcement priorities."). To the best of Plaintiff's knowledge, FDA has not issued a warning letter or taken any other form of enforcement action against manufacturers that have a PMTA on file and have not received an RTA or marketing denial order.

26. This also holds true for manufacturers who initially received a marketing denial order but where FDA either administratively stayed or withdrew that order. *See*, *e.g.*, *Turning Point Brands, Inc. v. FDA*, No. 21-3855, ECF No. 19 (6th Cir. Oct. 8, 2021); *My Vape Order, Inc. v. FDA*, No. 21-71302, ECF No. 45 (9th Cir. Dec. 30, 2021); *JUUL Labs, Inc. v. FDA*, No. 22-1123, Doc. #1953737 (D.C. Cir. July 6, 2022).

Application of the TCA and Deeming Rule to Synthetic Nicotine ENDS

27. When the Deeming Rule was adopted, the TCA only governed ENDS containing nicotine derived from tobacco. 21 U.S.C. § 321(rr) (2016). As a result, any product containing nicotine made from any other source (e.g., chemically-derived or synthetic nicotine) was not subject to regulation under the TCA or the Deeming Rule, including the PMTA requirements.

28. However, on March 15, 2022, Congress addressed this issue in the Consolidated Appropriations Act of 2022, Pub. L. No. 117-103, 136 Stat. 49, 741, § 111(a) (2022), in which it amended the statutory definition of "tobacco product" under the Food, Drug and Cosmetic Act

("FDCA") to include products containing nicotine "from any source," thus capturing ENDS products manufactured with synthetic nicotine.

29. The expanded statutory definition of "tobacco product" took effect on April 15, 2022, with manufacturers now being given only a month to submit PMTAs for synthetic nicotine ENDS by May 14, 2022. Products included in a timely-submitted PMTA were then afforded a grace period from FDA enforcement until July 13, 2022. *Id.* at § 111(d).

30. Like ENDS manufactured with nicotine derived from tobacco, FDA has continued to exercise enforcement discretion, at least with respect to such products with pending PMTAs. Again, to the best of Plaintiff's knowledge, FDA has not issued a warning letter or taken any other form of enforcement action against manufacturers of synthetic nicotine ENDS products with a timely submitted, pending PMTA.

The TCA's and FDA's PMTA Requirements

31. The TCA, FDA's regulations, and Agency guidance impose costly and time-consuming obligations on manufacturers to comply with the PMTA requirements. Under the TCA, FDA must conduct a complex, multi-disciplinary, science-based evaluation based on all data and information submitted by the applicant. Specifically, the manufacturer must demonstrate to FDA's satisfaction that the ENDS product is "appropriate for the protection of the public health" ("APPH"). The TCA requires the applicant to submit and FDA to consider a wide range of evidence, including: (i) the health risks of the product, including whether the product presents less risk than other tobacco products (like traditional cigarettes); (ii) a full statement of the components, ingredients, additives, and operation principles of the ENDS; (iii) labeling proposed to be used with the product; (iv) ENDS product samples; and (v) any other information considered relevant and requested by FDA to be included in the application. 21 U.S.C. § 387j(b).

32. The TCA also directs FDA to assess "with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account – (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products [otherwise known as "cessation"]; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products" [otherwise known as "initiation"]. 21 U.S.C. § 387j(c)(4).

33. FDA's PMTA regulations and guidance documents are even more detailed when instructing manufacturers on what is needed to demonstrate that an ENDS product is APPH. The PMTA rule, which was not finalized and promulgated until October 2021, lists numerous types of information and data that should be included in an application. 86 Fed. Reg. 55300 (Oct. 4, 2021) (codifying 21 C.F.R. § 1114.7). These include health risk studies, toxicological and pharmacological testing, public scientific literature reviews, pharmacokinetic evaluations, consumer perception and intention studies, and sales and marketing restrictions guarding against underage use. The final PMTA guidance document, which was initially published in 2019 and sets forth similar information and data requirements, runs over 50 pages. FDA, *Guidance for Industry, Premarket Tobacco Applications for Electronic Nicotine Delivery Systems (Revised)* (March 2023), https://tinyurl.com/mrfexddz. As a consequence, it is no surprise that PMTAs often take several years to prepare, easily costing millions of dollars even for just a few ENDS products.

34. When preparing a PMTA, a manufacturer may rely on and cross reference Tobacco Product Master Files ("TPMF"), which contain information (often proprietary) submitted to FDA by a third-party. For example, a third-party company that makes a flavor used by a manufacturer may submit a TPMF with the flavor's proprietary ingredients. Under FDA's regulations, 21 C.F.R. § 1114.7(b)(2), the manufacturer must provide "documentation" to FDA showing it has

authorization from the third-party to cross reference the TPMF. This "documentation" can, but is not required to, take the form of a separate Letter of Authorization ("LOA") provided to the manufacturer by the TPMF submitter.

35. Overall, the PMTA review process consists of three phases – acceptance, filing, and substantive (or scientific) review. The acceptance phase is governed by a 2016 regulation (21 C.F.R. § 1105.10) and the filing phase by a 2014 FDA memo posted on its website, https://tinyurl.com/2wax428w, with both phases formalized in the recently adopted PMTA final rule (21 C.F.R. § 1114.27). These two phases act as screening exercises in which FDA determines whether the PMTAs contain basic information, as well as sufficient data, to permit the more comprehensive scientific review. The RTAs in this case were issued after acceptance review.

36. Once the PMTA is submitted, the manufacturer may submit amendments to the PMTA before FDA issues a final decision. 21 C.F.R. § 1114.9. The amendment must include a reference to the Submission Tracking Number ("STN") previously assigned by FDA to the original PMTA submission. The amendment must also include a certification that is signed by an authorized representative of the manufacturer stating, among other things, that information in the application is true and correct, that no material facts have been omitted, and that the signatory is authorized to sign on the manufacturer's behalf. 21 C.F.R. §§ 1114.7(m), 1114.9.

37. As part of the PMTA process, there are several forms that FDA requests manufacturers to use depending on the submission involved. For an initial PMTA, there is Form 4057 – *Premarket Tobacco Product Application (PMTA) Submission*. This includes basic information like the name, address, and contact information of the applicant and authorized representative, the name and address of the manufacturing facilities, and the type of PMTA submission (e.g., standard PMTA or amendment). 21 C.F.R. § 1114.7(b).

38. FDA's PMTA regulations also allow manufacturers, for efficiency purposes, to combine or "bundle" PMTAs for multiple products. For bundled PMTAs, there is Form 4057b – *Premarket Tobacco Product Application Product Grouping Spreadsheet*. 21 C.F.R. § 1114.7(b).

39. The office of Management and Budget ("OMB") approved FDA's use of Form 4057b for the PMTAs in March 2020. This original version of the spreadsheet requested applicants to provide certain basic company and product information to characterize the bundled products, including the applicant name, product category and subcategory, and unique product identifiers (*see* Columns A-BF requiring product name, package type, product quantity, units, product quantity mass, characterizing flavor, tobacco cut style, portion count, portion mass, length description, length/width/diameter description, diameter format, portion thickness, ventilation, e-liquid volume, nicotine concentration, propylene glycol/vegetable glycerin ("PG/VG") ratio, wattage, battery capacity, tip type, wrapper material, number of hoses, source of energy, height, and additional properties).

40. On April 13, 2022, two days before the amended definition of "tobacco products" (now applying to synthetic nicotine ENDS) was adopted under the Consolidated Appropriations Act of 2022, FDA requested emergency authority from OMB to amend Form 4057b. The updated version required all the same information as the original Form 4057b, with a few minor additions requesting the Tobacco Product (TP) number (applicable only to products produced in U.S. domestic facilities), application type, filter ventilation, nicotine source, and the PG and VG value.

41. However, FDA did not reference this amended Form 4057b on its website where manufacturers could access it until April 28, 2022, just over two weeks before the statutory PMTA deadline of May 14, 2022 for synthetic nicotine ENDS products.

42. FDA also did not officially publish notice of the amended Form 4057b in the Federal Register until May 16, 2022, two days *after* the statutory filing deadline. 87 Fed. Reg. 29749 (May 16, 2022).

43. Finally, there is Form 4057a – *Premarket Tobacco Product Application Amendment and General Correspondence Application* – which is used when a manufacturer files an amendment to a PMTA. That form includes a certification signed by an authorized company official that, *inter alia*, verifies certain information contained in the amendment.

Pastel Cartel's PMTAs

44. Pastel Cartel filed bundled and individual PMTAs on May 14, 2022, the statutory PMTA deadline for filing synthetic nicotine ENDS and qualifying for the 90-day enforcement discretion period. The PMTAs covered over 100 non-tobacco flavored, synthetic nicotine ENDS, both disposables and stand-alone, bottled e-liquids.

45. Those products are identified by the following STNs: PM0005731.PD1-PD47, PM0005859.PD1-PD14, PM0005805.PD1, PM00005832.PD1, PM0005878.PD1, PM0005889.PD1-PD28, PM0005906.PD1, PM0005874.PD1-PD19, and PM0005904.PD1-PD4.

46. Pastel Cartel used an outside consultant, Arcus Compliance, to compile the PMTAs and submit them to FDA through the agency's electronic portal ("CTP Portal") by the statutory deadline, despite only having two months to prepare the applications after the TCA was amended to cover synthetic nicotine ENDS products.

47. Pastel Cartel has spent at least $7 million on its PMTAs and expects costs to eventually reach closer to the $9-10 million mark. These expenses cover, among other things, labs and product testing, a scientific literature review, product data collection, consultants and regulatory experts, attorneys, and employee time/wages. Just testing Pastel Cartel's products for

Harmful and Potentially Harmful Constituents ("HPHCs"), as required by 21 C.F.R. § 1114.7(k) and Agency guidance, has already cost around $2 million.

48. The PMTAs are thousands of pages long and contain more than 1 terabyte of information submitted to FDA.

49. As permitted by FDA's PMTA regulations, Pastel Cartel also filed amendments to the PMTAs before the RTAs were issued by FDA. These included amendments submitted on October 7, 2022 to replace the original Form 4057b with the updated version for each product in the bundled applications (while only the RTA for STNs PM0005731.PD1-PD47 identify the October 7, 2022 amendment in its Appendix B, the updated forms were filed via amendments for all products that received an RTA). Pastel Cartel also submitted amendments on October 18, 2022 for every product notifying FDA it had contracted with a third-party lab to conduct required testing for HPHCs. Finally, Pastel Cartel filed amendments on September 1, 2022 and September 14, 2022 for a subset of PMTAs – PM0005889.PD1-PD28 – correcting selected data errors regarding product ingredients and making clarifications to required environmental assessments.

50. Prior to the RTAs, Pastel Cartel began making plans to further amend the PMTAs. For instance, it is currently working with a third-party consultant, McKinney Regulatory Science Advisors, LLC ("McKinney"), to conduct an extensive longitudinal cohort study designed to evaluate Esco Bar flavors on the smoking behaviors of current adult smokers (the "Flavor Choice Study"). This research, which will have hundreds of participants at a minimum, aims to demonstrate that Esco Bar disposable ENDS and bottled e-liquid products have a positive impact on consumer desire and ability to switch away from traditional cigarettes and that a variety of flavor options, in addition to tobacco flavored ENDS, is critical to reducing cigarette consumption and complete switching. This study is expected to ultimately exceed $2 million.

51. FDA now requires that manufacturers submit the type of study being conducted by McKinney. To date, FDA has denied marketing authorization for every PMTA covering a non-tobacco flavored ENDS product simply because the PMTA did not contain a clinical trial, longitudinal study, or a similar study comparing the cessation efficacy of a manufacturer's non-tobacco and tobacco flavored products. In those instances where a marketing denial order was issued, the PMTAs made it through the acceptance and filing phases, but were not scientifically reviewed by FDA beyond looking for the existence or absence of such a study.

52. As discussed below, FDA's issuance of the RTAs will delay the Agency's consideration of this study and has otherwise resulted in on-going irreparable harm.

FDA's RTAs

53. On December 7-9, 2022, FDA issued nine RTAs for Pastel Cartel's PMTAs. **Ex. A**. They are largely identical and rely, with a few exceptions, on the same allegations for rejecting each PMTA. In issuing the RTAs, FDA ignored relevant evidence, never articulated any lawful grounds for denying the PMTAs, and violated the TCA and its own regulations and guidance.

54. **First**, FDA claims that Pastel Cartel referenced three TPMFs in each PMTA – Capella Flavors (MF0000401), Cardno ChemRisk (MF0000403), and Liquid Nicotine Wholesalers (MF0000470) – but did not provide documentation of their right to reference these TPMFs in the form of Letters of Authorization ("LOAs").

55. But only a quick review of the PMTAs would have revealed that FDA was incorrect. In its e-liquid PMTAs (STN PM0005889.PD1-PD28), Pastel Cartel provided LOAs for MF0000401 and MF0000470. The PMTAs covering the disposable Esco Bar products did not reference MF0000401 and MF0000470 and thus did not require LOAs.

56. Moreover, while Pastel Cartel inadvertently failed to provide an LOA for MF0000403 in all PMTAs, there was clear "documentation," as required by 21 C.F.R. § 1114.7(b)(2), in each PMTA that Pastel Cartel had been given authorization to reference that particular TPMF. MF0000403 is not a TPMF for proprietary ingredients or other components used in the company's ENDS products; rather, it is a scientific literature review conducted by a third-party consultant, Cardno ChemRisk, that numerous companies, as part of a coalition effort, came together to fund in order to be able to include the relevant scientific literature, a key requirement, in their PMTAs. Pastel Cartel was one of many paid members of the coalition at the time the PMTAs were filed which gave the company access to the TPMF.

57. Each of Pastel Cartel's PMTAs include electronic files, scientific literature review summaries, and quotations from MF0000403 that serve as documentation of the company's right to reference the TPMF, as such information could only have been furnished if Pastel Cartel had such authorization and access to the TPMF.

58. Specifically, MF0000403 contains an extensive literature review that evaluates the current state of the science on ENDS and e-liquids, and their impact on public health for the U.S. population, including both users and non-users of these products. Each of Pastel Cartel's PMTAs relied heavily on MF0000403. In fact, the main PMTA document in each of the company's applications (File name: "PastelCartelLLC_PMTA") essentially mirrors the state of science summary report in the TPMF, and includes numerous references to the information and studies contained in the TPMF – (i) an ENDS and e-liquid state of science report; and (ii) references to specific subject matter databases (abuse liability, adverse events, biomarkers, indoor air quality and second hand exposures, cessation, explosions, cardiovascular disease, initiation, topography, respiratory, perception, transition, *in vitro* toxicology, *in vivo* toxicology – in Modules 2.6 (Clinical

– Individual Health Overview), 2.6.3.2 (Abuse Liability), 2.6.3.3 (Topography and Product Use), 2.9 (Index of All Referenced Literature), 4.6 (Nonclinical Literature Review), 5.5 (Adverse Experience Reports), 5.6 (Individual Health Literature Review), and 6.8 (Population Health Literature Review). Further, Module 4.8 (Literature Review) includes a list of all referenced literature used to develop the databases in MF0000403. In fact, the only information included in the TPMF but not the PMTA was a full copy of each published article used to create the databases, which FDA would already have had access to. Based on this, FDA knew or should have known that Pastel Cartel was an authorized party to MF0000403 even in the absence of an LOA.

59. In rejecting the PMTAs on these grounds, FDA also ignored its own internal guidance. An FDA memo dated June 1, 2022 (process for implementing acceptance reviews), which was months before FDA issued the RTAs in this case, indicated that a missing LOA is not grounds for issuing a RTA and that, instead, FDA should contact the applicant. If the applicant cannot provide an LOA, which would not have been the case if FDA had simply contacted Pastel Cartel, the internal guidance says that FDA should not reject the PMTA. Rather, FDA should have continued the application review as if the applicant had never referenced the TPMF.

60. In the RTAs, FDA provided no explanation as to why multi-million dollar PMTAs should be denied in full merely because, in FDA's opinion, there was insufficient documentation indicating authorization to use a single TPMF. Again, FDA ignored relevant evidence as to "documentation" establishing authorization and acted contrary to its own regulations and guidance. In fact, nothing in the TCA or FDA's regulations and guidance even require applicants to rely on TPMFs. According to FDA, manufacturers may opt to incorporate by reference TPMFs to make the process more efficient, but it is completely voluntary on the applicant's part.

61. **Second**, FDA claims that the October, 7, 2022 and October 18, 2022 amendments filed for all products, as well as the September 1, 2022 and September 14, 2022 amendments regarding selected PMTAs, did not include the required certification and authorized signature.

62. Again, a quick review of the PMTAs would have revealed that FDA was mistaken. Each of the amendments listed the STNs corresponding to the amended PMTAs and included a Form 4057a, which contain the required certification and authorized signature by company CEO Darrell Suriff in Section VI (Certification Statement) of each Form 4057a. FDA clearly ignored relevant evidence, did not explain in the RTAs why the PMTAs should have otherwise been denied given that the requisite forms were submitted, and clearly acted in an unlawful manner by ignoring its own regulations and guidance.

63. **Third**, FDA claims that none of the original PMTAs included the Form 4057.

64. Although FDA is correct that the company's PMTAs did not attach the Form 4057, all of the information required to be included in that form was in each application and easily located by FDA in Module 1 of the PMTA main document (File name: PastelCartellLLC PMTA) and Module 1.3 Administrative Information files, PMTA Certification Statement (File name: PMTA CertificationStatement). These files include the applicant and manufacturer identification information, PMTA certification statement, and each tobacco product identification information, respectively. FDA cannot stick its head in the sand and ignore relevant evidence in its possession.

65. **Fourth**, FDA claims that none of the PMTAs included the amended Form 4057b. While FDA is correct that the PMTAs did not attach the amended Form 4057b, Pastel Cartel was not aware of the amendment because FDA did not publish the updated form in the Federal Register until two days after the company filed the PMTAs for synthetic nicotine ENDS by the May 14,

2022 statutory deadline. Pastel Cartel cannot be blamed for FDA's own shortcomings and failure to provide anything resembling fair notice and due process.

66. In any event, the PMTAs did include the 2020 version of the Form 4057b and all of the additional information that was required by the amended Form 4057b. FDA cannot ignore relevant evidence in its possession. It must explain, even though the applications contained all of the requested information, why they should have been denied.

67. Again, the fact that FDA could readily access this information is demonstrated by each RTA itself – Appendix A to each RTA includes all the applicable information that FDA claimed was missing because the updated Form 4057b was not included.

68. Moreover, once Pastel Cartel became aware of the amended Form 4057b, it submitted timely amendments for all bundled PMTAs on October 7, 2022 with the updated forms.

69. Finally, FDA also is incorrect that Form 4057b was required for each PMTA. Form 4057b only applies to "bundled" PMTAs. So FDA's claims do not apply to three non-bundled PMTAs – PM0005805.PD1, PM0005832.PD1, and PM0005878.PD1.

70. In the final analysis, FDA had in its possession all of the information required for PMTAs at the time they were filed and/or by virtue of the timely filed amendments. It was only due to FDA's insufficient (and apparently cursory) review of the PMTAs and other submissions did the Agency believe (incorrectly) that RTAs should be issued.

71. In fact, Pastel Cartel became even more concerned about FDA's lack of due diligence when following FDA's instructions in responding to each RTA. Specifically, each RTA identified a Regulatory Health Project Manager, named Anand Chandrasekhar, as the FDA staffer to contact regarding the RTA. **Ex. A**. However, when Pastel Cartel called the listed number to talk with Mr. Chandrasekhar, it became readily apparent that the RTAs had listed his cell phone

number. Pastel Cartel was finally able to reach Mr. Chandrasekhar after several weeks of calls, at which time Mr. Chandrasekhar informed the company that he no longer worked at FDA and had left the Agency in July 2022, a half-year *before* the RTAs were issued. This slipshod treatment strongly implies that the RTAs were not much more than cookie-cutter templates and raises serious questions regarding FDA's conduct in this matter.

72. It took FDA almost seven months just to conduct the acceptance review.

Pastel Cartel's Irreparable Harm

73. The RTAs will result in significant on-going irreparable harm.

74. **First**, as discussed above, once the RTAs were issued, Pastel Cartel could no longer submit amendments to the PMTAs that would otherwise be considered as part of an on-going review of the applications. 21 C.F.R. § 1114.9. While a manufacturer may re-submit a PMTA which corrects any shortcomings identified in the application, that PMTA goes back to the beginning of FDA's review procedures to start the process anew. Specifically, the application must once again go through the acceptance and filing review phases before reaching the comprehensive substantive or scientific review stage.

75. As a result, Pastel Cartel will face significant delays in obtaining a final resolution to its PMTAs. It will take longer for FDA to complete a review of any new PMTAs filed by Pastel Cartel that contain the results of the Flavor Choice Study (which McKinney had initially scheduled for completion in September 2023) when compared to applications that are already in the review queue. Indeed, it took FDA almost seven months just to complete the acceptance review of the company's PMTAs. As long as the RTAs are in place and Pastel Cartel cannot simply file amendments with the Flavor Choice Study results or other information, the company will have to submit new PMTAs and essentially wait its turn to begin review all over again.

76. Significant delays will have further adverse impacts on the company. As uncertainty regarding the ultimate outcome of the PMTA review continues to linger, Pastel Cartel will be forced to look at other business models (such as expanding internationally) and incur associated costs in a desperate effort to stay in business. Similarly, the company will be unable to continue growing the business and its brand, as it has over the past decade, such as increasing inventory and the number of employees. And the company will continue to lose market share and goodwill as uncertainty regarding the regulatory status of its products remains. Indeed, substantial delays would likely force Pastel Cartel out of business.

77. **Second**, the TCA requires FDA to promulgate regulations to allow manufacturers to use products that have not been granted market authorization for investigational purposes. 21 U.S.C. § 387j(g). To date, FDA has not promulgated those regulations. Instead, it is exercising enforcement discretion when deciding whether a manufacturer must file an Investigational Tobacco Product ("ITP") application to use such products for clinical studies and obtain approval before commencing any study. *See* FDA, *Use of Investigational Tobacco Products: Guidance for Industry and Investigators* (Feb. 2019), at 1, https://tinyurl.com/4ckyerzm.

78. Due to FDA's exercise of enforcement discretion, McKinney would have proceeded with the Flavor Choice Study without completing an ITP application if the RTAs had not been issued. That is because FDA in its enforcement discretion has not been requiring ITPs for commercialized products that have not received an RTA or other PMTA denial. However, because FDA has issued RTAs to Pastel Cartel, McKinney filed an ITP application for the Flavor Choice Study at the request of FDA in May 2023.

79. FDA's review and approval of the ITP application will lead to further delays and costs. McKinney submitted the application for that study almost four months ago and still does

not have approval to proceed. In the meantime, Pastel Cartel paid McKinney over $30,000 to complete the ITP application and has spent another $60,000 to continue reserving limited lab space in the event FDA approves the application soon. If the RTAs remain in place and FDA does not approve the ITP application in the very near future, Pastel Cartel will have to continue paying to reserve lab space for the Flavor Choice Study at about $20,000 per month and incur further delays in FDA completing the PMTA review process.

80. If the RTAs are stayed, however, McKinney would be able to move ahead with the Flavor Choice Study.

Violations of the Administrative Procedure Act ("APA")

81. Pastel Cartel reasserts and incorporates by reference each of the proceeding paragraphs.

82. The RTAs constitute "final agency action" under the APA and/or otherwise under appliable law. 5 U.S.C. § 704.

83. The APA proscribes agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). Moreover, agency action must be set aside if it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). Finally, an agency action must be supported by "substantial evidence." 5 U.S.C. § 706(2)(E).

84. Under these provisions, at a minimum, agency action is unlawful if the agency failed to articulate a rational connection between the facts found and the choice made, failed to consider an important aspect of the problem, or offered an explanation for its decision that runs counter to the evidence. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

85. In the following instances, FDA violated the APA as referenced above, including by acting in an arbitrary, capricious, and unlawful manner, when the RTAs failed to cite any substantial evidence in support, explain why denying the PMTAs was otherwise warranted, or comply with the TCA and the Agency's regulations and guidance:

a. FDA violated the APA when it issued RTAs based on two LOAs (MF0000401 and MF0000470) and Form 4057a certifications/authorizations for four PMTA amendments submitted by the company (September 1 and 14, and October 7 and 18, 2022) that were allegedly missing. Those LOAs and Form 4057a certifications/authorizations were, in fact, in FDA's possession. *See*, *e.g.*, 21 C.F.R. §§ 1114(b)(2), (c), (m), 1114.9; 86 Fed. Reg. at 55316.

b. FDA violated the APA when it issued RTAs based on one LOA (MF0000403) that was inadvertently omitted because there was otherwise adequate "documentation" contained in the PMTAs clearly indicating that Pastel Cartel had authority to reference that TPMF. 21 C.F.R. §§ 1114(b)(2); 86 Fed. Reg. at 55316. FDA also violated the APA in not adhering to its own internal guidance for resolving missing LOAs when it denied the PMTAs instead of either contacting Pastel Cartel to obtain the LOA or reviewing the PMTAs without cross-referencing the TPMF.

c. FDA violated the APA when it issued the RTAs due to the absence of Form 4057 in the PMTAs because all information to be included in the form was otherwise in the PMTAs and easily located by the Agency. 21 C.F.R. § 1114.7(c).

d. FDA violated the APA when it issued the RTAs because an amended Form 4057b was inadvertently omitted from the PMTAs where a previous version of the form was submitted, all of the information required by Form 4057b was otherwise included in

the PMTAs and easily found by the Agency, and FDA failed to give Pastel Cartel adequate notice that it should have used the amended form prior to the May 14, 2022 statutory deadline for filing PMTAs. 21 C.F.R. § 1114.7(c). Moreover, three PMTAs (PM0005805.PD1, PM0005832.PD1, and PM0005878.PD1) were wrongfully denied based on these grounds because they were not bundled PMTAs subject to the form requirement. Finally, once Pastel Cartel became aware of the amended Form 4057b, it filed amendments containing those forms, which were subsequently rejected, as discussed above, based on the incorrect premise that those amendments did not contain the proper certifications/authorizations. 21 C.F.R. § 1114.9.

86. In the final analysis, it was wholly arbitrary and capricious, as well as unlawful, for FDA to deny the PMTAs and issue the RTAs based on the Agency's own mistakes and minor omissions by the company, particularly where these applications cost the company millions of dollars to complete and ultimately contained all of the information required FDA.

87. As a direct and immediate result of FDA's actions in violation of the APA, Pastel Cartel is suffering, as discussed above, on-going irreparable harm.

COUNT II

Violation of the APA and the Due Process Clause of the Fifth Amendment Failure to Provide Fair Notice

88. Pastel Cartel reasserts and incorporates by reference each of the preceding paragraphs.

89. A fundamental principle of our regulatory system is that agencies must give fair notice of conduct that is required. An entity should be able to discern with "ascertainable certainty" through regulations and other public statements what the agency considers to be

unlawful prior to engaging in regulated activity. It is arbitrary and capricious, and a violation of due process, for an agency not to provide fair warning of what is demanded for compliance.

90. FDA failed to give Pastel Cartel fair notice of the amended Form 4057b before the May 14, 2022 statutory deadline for filing PMTAs covering synthetic nicotine ENDS products. Only several weeks before the statutory deadline did the Agency quietly place the amended form on its website, without any notice that it had updated the form. And FDA did not provide official notice in the Federal Register until two days *after* the deadline. And then FDA refused to accept Pastel Cartel's amendments containing the updated forms because it mistakenly believed that the amendments did not contain required company certifications.

91. Given the lack of any fair warning from FDA, Pastel Cartel could not have ascertained with certainty that an amended Form 4057b had to be included in the PMTAs for its synthetic ENDS products.

92. As a direct and immediate result of FDA's failure to provide fair notice, Pastel Cartel is suffering, as previously described, on-going irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Pastel Cartel respectfully requests the following relief:

a. A declaration that the RTAs violate the APA;

b. A declaration that the RTAs, to the extent that they are based on an alleged failure to include the amended Form 4057b, violate the Due Process Clause of the Fifth Amendment;

c. An order vacating and setting aside the RTAs, and remanding the PMTAs back to FDA for further review in accordance with the law;

d. An order granting preliminary and permanent injunctive relief;

e. An award granting Pastel Cartel reasonable attorneys' fees, costs, and expenses, including, but not limited to, under 28 U.S.C. § 2412;

f. A trial by jury; and

g. An award of such further relief as this Court deems appropriate.

Dated: August 25, 2023

/s/ Michael C. Smith
State Bar No. 18650410
SCHEEF & STONE, LLP
113 East Austin Street
Marshall, TX 75670
Phone: (903) 938-8900
Michael.Smith@solidcounsel.com

Eric P. Gotting
Azim Chowdhury
Pro Hac Vice Applications To Be Filed
KELLER AND HECKMAN LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001
Phone: (202) 434-4100
gotting@khlaw.com
chowdhury@khlaw.com

Counsel for Plaintiff